

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of:	Freier, <i>et al.</i>	Confirmation No.:	2330
Application No.:	10/511,832	Art Unit:	1635
Filed:	January 3, 2006	Examiner:	McGarry, Sean
For:	ANTISENSE MODULATION OF HYDROXYSTEROID 11- BETA DEHYDROGENASE 1 EXPRESSION	Attorney Docket No:	RTS-0428USA

**REQUEST FOR RECONSIDERATION OF  
PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)**

**Mail Stop PETITION**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants received a Notice of Allowance mailed June 9, 2010 from the U.S. Patent and Trademark Office (“PTO”) in connection with Application 10/511,832 (hereinafter “the ‘832 application”), which indicates that the issue fee for the ‘832 application is due by September 9, 2010. Accompanying the Notice of Allowance was a Determination of Patent Term Adjustment under 35 U.S.C. 154(b), indicating that the patent term adjustment to date was 136 days for the ‘832 application.

Applicants hereby respectfully request reconsideration of the patent term adjustment indicated in the Notice of Allowance and in the above-identified patent. Specifically, Applicants believe that the patent term adjustment should be increased by 149 days to a total of 285 days. The basis for this petition and the required fees are set forth below.

**REMARKS**

A request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(b) must be accompanied by:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
  - (i) the correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
  - (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
  - (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
  - (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or  
(B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

*See 37 C.F.R. § 1.705(b).*

In support of this request, Applicants submit the following:

**1. Fee Required Under 37 C.F.R. § 1.705(b)(1)**

Pursuant to 37 C.F.R. §§ 1.705(b)(1) and § 1.18(e), the fee required for filing this application is believed to be \$200.00.

Please charge the required fee to Isis Pharmaceuticals Deposit Account No. 50-0252 (referencing docket no. RTS-0428USA).

**2. Statement Required Under 37 C.F.R. § 1.705(b)(2)**

Pursuant to 37 C.F.R. § 1.702(b)(2), Applicants submit the following statement of facts in support of this application:

- (i) The correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment are as follows:

1. Correct patent term adjustment:

The correct patent term adjustment is 285 days, which is attributable to (a) the failure of the PTO to mail a notification under 35 U.S.C. § 132 not later than fourteen months after the date on which the ‘832 application was filed under 35 U.S.C. 111(a) (delay under 37 C.F.R. § 1.702(a)(1)); (b) the failure of the PTO to reply no later than four months after the applicant replied under 35 U.S.C. § 132 (a response to a Non-final Office Action) (delay under 37 C.F.R. § 1.702(a)(2)); and (c) the failure of the PTO to issue a patent within three years of the actual filing date of the ‘832 application (delay under 37 C.F.R. § 1.702(b)).

2. Bases under 37 C.F.R. § 1.702 for the adjustment:

(a) Delay under 37 C.F.R. § 1.702(a)(1)

The delay by the PTO under 37 C.F.R. § 1.702(a)(1) is 283 days.

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to mail a notification under 35 U.S.C. § 132 within fourteen months from the date of filing of the ‘832 application. *See* PTO’s Patent Application Information Retrieval page for U.S. Application No. 10/511,832, at Patent Term Adjustment History (“PTO PAIR Adjustment,” Exhibit A). The ‘832 application was filed under 35 U.S.C. § 111(a) on January 3, 2006. The first notification under 35 U.S.C. § 132 (a Restriction Requirement) was mailed by the PTO on December 11, 2007. Accordingly, the PTO did not mail a notification under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151 within fourteen months after the date on which the application was filed (or by March 3, 2007), and thus, the term of the patent should have been adjusted because the notification under 35 U.S.C. § 132 was delayed by 283 days, which is the period of time from March 3, 2007, to December 11, 2007. 37 C.F.R. § 1.702(a)(1).

(b) Delay under 37 C.F.R. § 1.702(a)(2)

The delay by the PTO under 37 C.F.R. § 1.702(a)(2) is 8 days.

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO did not respond to a reply under 35 U.S.C. § 132 (a response to a Non-final Office Action) or to an appeal taken under 35 U.S.C. § 134 within four months after the date on which the reply by the applicant was filed or the appeal was taken. Applicants filed a response to a non-final action on November 16, 2009. The first notification by the PTO under 35 U.S.C. § 132 after the response to Non-final Office Action was filed was on March 24, 2010. Accordingly, the PTO did not mail a reply under 35 U.S.C. § 132 or 35 U.S.C. § 134 within four months after the date on which the response to Non-final Office Action was filed (or by March 16, 2010), and thus, the term of the patent should have been adjusted because the notification under 35 U.S.C. § 132 was delayed by 8 days, which is the period of time from March 16, 2010, to March 24, 2010. *See* 37 C.F.R. § 1.702(a)(2).

(c) Delay under 37 C.F.R. § 1.702(b)

The delay by the PTO under 37 C.F.R. § 1.702(b) is 149 days.

The ‘832 application was filed under 35 U.S.C. § 111(a) on January 3, 2006. A Request for Continued Examination (“RCE”) under 35 U.S.C. § 132(b) was filed on June 2, 2009. The filing of a RCE cuts-off the applicant’s ability to accumulate any additional patent term adjustment against the three-year pendency provision, but does not otherwise affect patent term adjustment.” *See* MPEP § 706.07(h) XIII A. “Comparison With The Transitional Procedure Set Forth In 37 CFR 1.129(a) And The CPA Procedure Set Forth In 37 CFR 1.53(d).” Accordingly, the PTO failed to issue a patent within three years of the date on which the application was filed (or by January 4, 2009), and thus, the term of the patent should have been adjusted because issuance was delayed by 149 days, which is the period of time from January 4, 2009, to June 2, 2009. 37 C.F.R. § 1.702(b). This delay in issuance of the patent was not included by the PTO in its calculation of patent term adjustment (*see* “PTO PAIR Adjustment,” Exhibit A).

According to 35 U.S.C. § 154(b)(2)(A): “To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” See 35 U.S.C. § 154(b)(2)(A).

According to 37 C.F.R. § 1.703(f): “The term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, to the extent that such periods are not overlapping ....” (emphasis added).  
See 37 C.F.R. § 1.703(f).

Applicants respectfully submit that under controlling case law the delay under 37 C.F.R. § 1.702(a)(1), 37 C.F.R. § 1.702(a)(2), and 37 C.F.R. § 1.702(b) do not overlap for the ‘732 application.

In *Wyeth et al. v. Dudas* (hereinafter *Wyeth*) the District Court for the District of Columbia clarified the meaning of 35 U.S.C. § 154(b)(2)(A). See *Wyeth et al. v. Dudas*, Civil Action No. 07-1492 (JR), United States District Court for the District of Columbia, 2008 U.S. Dist. LEXIS 76063 (D.D.C., September 30, 2008), attached hereto as Exhibit B. In *Wyeth*, the court held that: “The only way that periods of time can ‘overlap’ is if they occur on the same day. If an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap.” *Wyeth*, 2008 U.S. Dist. LEXIS 76063, 9-10.

Turning to the ‘832 application, the period of delay under 37 C.F.R. § 1.702(a)(1) occurred from March 3, 2007, fourteen months from the date on which the application was filed, to December 11, 2007, the date on which a Restriction Requirement was mailed by the PTO. The period of delay under 37 C.F.R. § 1.702(a)(2) occurred from March 16, 2010, four months from the date on which the Applicant filed a response to Non-final Office Action, to March 24, 2010, the date on which the PTO replied to Applicants response. The period of delay under 37 C.F.R. § 1.702(b) occurred from January 4, 2009, three years from the date on which the application was filed, to June 2,

2009 the date a Request for Continued Examination was filed. Thus, the delays under 37 C.F.R. § 1.702(a)(1) (March 3, 2007 to December 11, 2007), 37 C.F.R. § 1.702(a)(2) (March 16, 2010 to March 24, 2010), and 37 C.F.R. § 1.702(b) (January 4, 2009 to June 2, 2009) occurred on different calendar days. Consequently, under 35 U.S.C. § 154(b)(2)(A), the delay under 37 C.F.R. § 1.702(a)(1), 37 C.F.R. § 1.702(a)(2), and 37 C.F.R. § 1.702(b) do not overlap each other, and therefore the total delay under 37 C.F.R. § 1.702 for the adjustment should be a summation of the delays under 37 C.F.R. § 1.702(a)(1), 37 C.F.R. § 1.702(a)(2), and 37 C.F.R. § 1.702(b), or 440 days (the sum of 283, 8 and 149 days).

- (ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) are as follows:

1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e):

An adjustment is sought under 37 C.F.R. § 1.703(a)(1), which provides, in relevant part, that the period of adjustment is “[t]he number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first.”

The patent term adjustment calculated by the PTO correctly included the time period under 37 C.F.R. § 1.702(a)(1) for the period beginning March 3, 2007 (fourteen months after the date on which the ‘832 application was filed), and ending December 11, 2007, the date the Restriction Requirement was mailed from the PTO. Applicants confirm that this period consists of 283 days.

An adjustment is sought under 37 C.F.R. § 1.703(a)(2), which provides, in relevant part, that the period of adjustment is “response to a reply under 35 U.S.C. 132 or to an appeal taken under 35 U.S.C. 134 not later than

four months after the date on which the reply was filed or the appeal was taken.”

The patent term adjustment calculated by the PTO correctly included the time period under 37 C.F.R. § 1.702(a)(2) for the period beginning March 16, 2010, four months after the date on which Applicant’s response to Non-final Office Action was filed, and ending March 24, 2010, the date the Notice of Allowance was mailed. Applicants confirm that this period consists of 8 days.

An adjustment is sought under 37 C.F.R. § 1.703(b), which provides, in relevant part, that “the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a)... and ending on the date a patent was issued.” This period of adjustment, however, does not include “[t]he number of days, if any, in the period beginning on the date which a request for continued examination of the application under 35 U.S.C. § 132(b) was filed and ending on the date the patent was issued.” 37 C.F.R. § 1.703(b)(1).

Applicants submit that this period consists of 149 days. Applicants further submit that the delay under 37 C.F.R. § 1.702(a)(1) and 37 C.F.R. § 1.702(b) do not overlap, as explained above.

Accordingly, Applicants’ believe that the delays attributable to the PTO under 37 C.F.R. § 1.702 total 440 days (the sum of 283, 8 and 149 days), not 269 days as calculated by the PTO.

## 2. Adjustment under 37 C.F.R. § 1.703(f):

As discussed in section (i) above, Applicants believe that the total delay by the PTO under 37 C.F.R. § 1.702(a)(1), (a)(2) and (b) amounts to 440 days. As discussed in section (iv) below, Applicants believe that the total delay attributable to Applicants under 37 C.F.R. § 1.704 amounts to 155 days. Applicants believe that the total period of adjustment due under 37 C.F.R.

§ 1.703(f) is 285 days, which is the sum of the periods by the PTO calculated under 37 C.F.R. §§ 1.702(a) through (e) (*i.e.*, 283 days), to the extent that such periods are not overlapping, less the sum of the periods calculated under Section 1.704 (*i.e.*, 155 days).

- (iii) The ‘832 application is not subject to a terminal disclaimer.
- (iv) The circumstances during the prosecution of the ‘832 application that might constitute a failure to engage in reasonable efforts to conclude processing or examination of the ‘832 application as set forth in 37 C.F.R. § 1.704 are believed to consist to consist of the following:
  1. a delay of 92 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants’ filing of an Amendment and Response on April 1, 2008, in response to the non-final Office Action mailed on April 1, 2008;
  2. a delay of 61 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants’ filing of Request for Continued Examination on June 2, 2009, in response to the non-final Office Action mailed on January 2, 2009;
  3. a delay of 2 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants’ filing of an Amendment and Response on November 16, 2009, in response to the non-final Office Action mailed on August 14, 2009.

37 C.F.R. § 1.704(b) provides, in relevant part: “[A]n applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request, measuring such three-month period from the date the notice or action was mailed or given to the applicant, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the

rejection, objection, argument, or other request and ending on the date the reply was filed.”

Applicants believe that the sum of the above time period under 37 C.F.R. § 1.704(b) is 155 days. Applicants respectfully submit that this time period is correctly calculated by the PTO. *See PTO PAIR Adjustment, Exhibit A.*

### **CONCLUSION**

In summary, the total adjustment under 37 C.F.R. § 1.702(a)(1), (a)(2) and (b) is 440 days, the total delay attributable to Applicants under 37 C.F.R. § 1.704 is 155 days, and thus the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 285 days. Accordingly, Applicants respectfully request an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling 285 days.

Applicants submit that the issues raised in this request for reconsideration of patent term adjustment are timely raised under 37 C.F.R. § 1.705(b), which provides in relevant part that ‘[a]n application for patent term adjustment under this section *must be filed no later than the payment of the issue fee...*’ (emphasis added).

Applicants submit that the issues raised in this request for reconsideration of patent term adjustment are timely raised under 37 C.F.R. § 1.705(b) for the following reason:

1. Applicants were informed of the allowance of the ‘832 application in the Notice of Allowance mailed June 9, 2010 from the PTO. Applicants could not have calculated the delay by the PTO under 37 C.F.R. § 1.702(b) until after they were informed of the date of allowance. Since Applicants could not have known of the total delay by the PTO until they received the Notice of Allowance, Applicants could not have raised the issue of the 149 days of PTO delay under 37 C.F.R. § 1.702(b) in an application for patent term adjust under 37 C.F.R. § 1.705(b).

Based on the OG notice dated September 10, 2009, Applicants are aware that the PTO does not calculate and inform the applicant of the patent term adjustment based upon the three-

year pendency provision of 35 U.S.C. §154(b)(1)(B) in the notice of allowance because it is the view of the PTO that it must know the date the patent will issue to be able to calculate the patent term adjustment based upon this provision. Therefore, the PTO has stated that “a request for reconsideration of the patent term adjustment calculation based on the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) will be considered timely under 37 CFR 1.705(d) if filed within two months of the date the patent issued.”

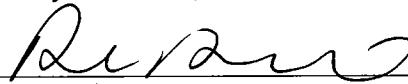
If the PTO views the above request for recalculation of PTA under the provision of 35 U.S.C. §154(b)(1)(B) as premature because the PTO must know the date the patent will issue, Applicants reserve the right to raise the issue under 37 C.F.R. 1.705(d) within two months of the date the patent issues, relying on the above statement in the OG notice dated September 10, 2009.

In accordance with 37 C.F.R. § 1.705(b), this request for reconsideration of patent term adjustment is being filed before payment of the issue fee and thus is timely under 37 C.F.R. § 1.705(b).

Respectfully submitted,

Date:

Aug. 20, 2010

For:   
Reena R. Desai  
Reena R. Desai  
**Isis Pharmaceuticals, Inc.**  
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53,833

**EXHIBIT A:**  
**PTO PAIR Adjustment**

10/511,832	ANTISENSE MODULATION OF HYDROXYSTEROID 11-BETA DEHYDROGENASE 1 EXPRESSION	08-12-2010:13:49:17
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### Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/511,832

Filing or 371(c) Date:	01-03-2006	USPTO Delay (PTO) Delay (days):	-
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	-	Applicant Delay (APPL) Delay (days):	-
Post-Issue Petitions (days):	-	Total PTA (days):	136
USPTO Adjustment(days):	-	Explanation Of Calculations	

### Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
06-09-2010	Mail Notice of Allowance		
06-05-2010	Document Verification		
06-05-2010	Notice of Allowance Data Verification Completed		
06-05-2010	Examiner's Amendment Communication		
05-27-2010	Information Disclosure Statement considered		
05-27-2010	Reference capture on IDS		
05-27-2010	Information Disclosure Statement (IDS) Filed		
05-27-2010	Request for Continued Examination (RCE)		
05-28-2010	Disposal for a RCE / CPA / R129		
05-27-2010	Information Disclosure Statement (IDS) Filed		
05-27-2010	Workflow - Request for RCE - Begin		
04-05-2010	Sequence Forwarded to Pubs on Tape		
03-24-2010	Electronic Review		
03-24-2010	Email Notification		
03-24-2010	Email Notification		
03-24-2010	Mail Examiner's Amendment		
03-24-2010	Mail Notice of Allowance	8	
03-17-2010	Document Verification	↑	
03-16-2010	Examiner's Amendment Communication	↑	
03-15-2010	Notice of Allowance Data Verification Completed	↑	
03-15-2010	Case Docketed to Examiner in GAU	↑	
01-10-2010	Date Forwarded to Examiner	↑	
11-16-2009	Response after Non-Final Action	2	
08-14-2009	Electronic Review	↑	
08-14-2009	Email Notification	↑	
08-14-2009	Mail Non-Final Rejection	↑	
08-12-2009	Non-Final Rejection		
06-04-2009	Date Forwarded to Examiner		
06-04-2009	Date Forwarded to Examiner		
06-02-2009	Request for Continued Examination (RCE)	61	
06-04-2009	Disposal for a RCE / CPA / R129	↑	

06-02-2009	Request for Extension of Time - Granted	↑
06-02-2009	Workflow - Request for RCE - Begin	↑
05-18-2009	Email Notification	↑
05-18-2009	Mail Advisory Action (PTOL - 303)	↑
05-13-2009	Advisory Action (PTOL-303)	↑
05-07-2009	Date Forwarded to Examiner	↑
05-04-2009	Amendment after Final Rejection	↑
05-04-2009	Request for Extension of Time - Granted	↑
01-02-2009	Mail Final Rejection (PTOL - 326)	↑
12-31-2008	Final Rejection	
11-02-2008	Date Forwarded to Examiner	
10-01-2008	Response after Non-Final Action	92
10-01-2008	Request for Extension of Time - Granted	↑
04-01-2008	Mail Non-Final Rejection	↑
03-17-2008	Non-Final Rejection	
01-26-2006	Information Disclosure Statement considered	
01-24-2008	Date Forwarded to Examiner	
01-08-2008	Response to Election / Restriction Filed	
12-11-2007	Mail Restriction Requirement	283
12-10-2007	Requirement for Restriction / Election	↑
06-27-2007	Correspondence Address Change	↑
06-27-2007	Change in Power of Attorney (May Include Associate POA)	↑
07-14-2006	Correspondence Address Change	↑
07-14-2006	Change in Power of Attorney (May Include Associate POA)	↑
02-28-2006	IFW TSS Processing by Tech Center Complete	↑
02-28-2006	Case Docketed to Examiner in GAU	↑
01-26-2006	Reference capture on IDS	↑
01-26-2006	Information Disclosure Statement (IDS) Filed	↑
01-26-2006	Information Disclosure Statement (IDS) Filed	↑
02-05-2006	Cleared by OIPE CSR	↑
02-05-2006	Cleared by OIPE CSR	↑
02-05-2006	Cleared by OIPE CSR	↑
02-05-2006	Cleared by OIPE CSR	↑
01-03-2006	371 Completion Date	↑
01-27-2006	Application Dispatched from OIPE	
01-27-2006	Notice of DO/EO Acceptance Mailed	
01-03-2006	Additional Application Filing Fees	
01-03-2006	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	

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**EXHIBIT B:**

***Wyeth et al. v. Dudas*, Civil Action No. 07-1492 (JR),  
United States District Court for the District of  
Columbia, 2008 U.S. Dist. LEXIS 76063 (D.D.C.,  
September 30, 2008)**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

WYETH, et al., :  
: :  
Plaintiffs, :  
: :  
v. : Civil Action No. 07-1492 (JR)  
: :  
JON W. DUDAS, Under Secretary of :  
Commerce for Intellectual :  
Property and Director of U.S. :  
Patent and Trademark Office, :  
: :  
Defendant. : :

**MEMORANDUM OPINION**

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. Section 154(a)(2) establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever the patent prosecution takes more than three years. 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap, Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds

specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

**Statutory Scheme**

Until 1994, patent terms were 17 years from the date of issuance. See 35 U.S.C. § 154 (1992) ("Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . . ."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. See Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which -- referred to as the Patent Term Guarantee Act of 1999 -- provided for the adjustments that are at issue in this case. Pub. L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in subsection (b) (1) (A), the “[g]uarantee of prompt Patent and Trademark Office response.” It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. See 35 U.S.C. § 154(b) (1) (A) (i)-(iv). Periods of delay that fit under this provision are called “A delays” or “A periods.” The second provision is the “[g]uarantee of no more than 3-year application pendency.” Under this provision, a one-day term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO.<sup>1</sup> See 35 U.S.C. § 154(b) (1) (B). The period that begins after the three-year window has closed is referred to as the “B delay” or the “B period”. (“C delays,” delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

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<sup>1</sup> Certain reasons for exceeding the three-year pendency period are excluded, see 35 U.S.C. § 154(b) (1) (b) (i)-(iii), as are periods attributable to the applicant’s own delay. See 35 U.S.C. § 154(b) (2) (C).

The extensions granted for A, B, and C delays are subject to the following limitation:

**(A) In general.**--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer the question of what is double-counting and what is not. Proper interpretation of this proscription against windfall extensions requires an assessment of what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. § 154(b)(3)(A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, see 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A), which was published on June 21, 2004, at 69 Fed. Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. § 154(b)(1)(B) (i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

69 Fed. Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is

1/1/07, but the patent does not issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends three years later, with the issuance of the patent on 1/1/08. In this example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

#### **Chevron Deference**

We must first decide whether the PTO's interpretation is entitled to deference under Chevron v. NRDC, 467 U.S. 837 (1984). No, the plaintiffs argue, because, under the Supreme Court's holdings in Gonzales v. Oregon, 546 U.S. 243 (2006), and United States v. Mead Corp., 533 U.S. 218 (2001), Congress has not "delegated authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority.

See Gonzales, 546 U.S. at 255-56, citing Mead, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded Chevron deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. See Merck & Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

Here, as in Merck, the authority of the PTO is limited to prescribing "regulations establishing procedures for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added) -- that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). Chevron deference does not apply to the interpretation at issue here.

**Statutory Construction**

Chevron would not save the PTO's interpretation, however, because it cannot be reconciled with the plain text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at Chevron's "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., MCI v. AT&T, 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether "periods of delay attributable to grounds specified in paragraph (1) overlap." The only way that periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its interpretation as essentially running the "period of delay" under subsection (B) from the filing date of the patent application, such that a period of "B delay" always overlaps with any periods of "A delay" for the purposes of applying § 154(b)(2)(A).

The problem with the PTO's construction is that it considers the application delayed under § 154(b)(1)(B) during the

period before it has been delayed. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension "not exceed the actual number of days the issuance of the patent was delayed," and by the PTO's view that "A delays" during the first three years of an applications' pendency inevitably lead to "B delays" in later years. Thus, as the PTO sees it, if plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet an administrative deadline, and again because that failure has pushed back the entire processing of the application into the "B period." Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that -- again from the PTO's viewpoint -- the applicant is not "compensated" for the PTO's administrative delay, he is benefitted by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and no more, it could easily have been written that way. It is true that the legislative context -- as

distinct from the legislative history -- suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided before GATT. But it chose to write a "[g]uarantee of no more than 3-year application pendency," 35 U.S.C. § 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to prevent windfall extensions may be reasonable -- they may even be consistent with Congress's intent -- but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

JAMES ROBERTSON  
United States District Judge

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

WYETH, et al., :  
: :  
Plaintiffs, :  
: :  
v. : Civil Action No. 07-1492 (JR)  
: :  
JON W. DUDAS, Under Secretary of :  
Commerce for Intellectual :  
Property and Director of U.S. :  
Patent and Trademark Office, :  
: :  
Defendant. : :

ORDER

For the reasons stated in the accompanying memorandum opinion, plaintiffs' motion for summary judgment [12] is **GRANTED** and defendant's motion for summary judgment [16] is **DENIED**. The case is remanded to the agency for further proceedings that are consistent with this opinion.

JAMES ROBERTSON  
United States District Judge